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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,878	01/25/2002	Gordhanbhai N. Patel	PATL 3. 0-012/PCT/US	1198
	7590	02/24/2005	EXAMINER CROSS, LATOYA I	
OMRI M. BEHR 325 PIERSON AVENUE EDISON, NJ 08837-3123			ART UNIT 1743	PAPER NUMBER
DATE MAILED: 02/24/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,878

Applicant(s)

PATEL

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 40-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is in response to Applicants' remarks filed on December 14, 2004.

Claims 1-11 and 40-45 are pending.

Withdrawal of Rejections from Previous Office Action

- The rejections over Larsson et al and Larsson et al in view of Ignacio et al are withdrawn in view of Applicants' arguments that Larsson et al fail to teach an activator comprised of a monovalent cation and an anion.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 6-11, 40-45 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,094,642 to Sumimoto et al.

Sumimoto et al teach an indicator device for ethylene oxide gas. The device comprises an indicator composition having a polymer, a coloring agent, and an activator. The polymer is preferably nitrocellulose. Other polymers, including vinyl chloride and vinyl acetate were also used (col. 2, lines 24-36; col. 3, lines 56-69). The coloring agent is preferably a blue coloring

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agent (col. 3, lines 6-21). The activator is a basic substance such as sodium carbonate having a monovalent cation and an anion (col. 2, lines 45-54). Example 1 teaches all of the components dissolved in a solvent (ethyl acetate). Sumimoto et al teach that when the composition is exposed to ethylene oxide gas, an observable color forms. With respect to the method of claims 40-45, Sumimoto et al teach that the indicator composition is prepared and applied to a packaging bag. The packaging bag having the indicator is exposed to sterilization gas mixture having ethylene oxide. After exposure, an observable color change from blue to green formed. See Example 1.

3. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,287,518 to Ignacio et al.

Ignacio et al teach sterilization monitoring devices. The device comprise a dye, a halogen source and a binder resin. The dye is a pH sensitive dye that, when exposed to sterilant, will produce a color change from yellow to blue, for example (see Example 2). The halogen source is a compound such as an alkali metal halide salt (potassium bromide, for example). See col. 3, lines 31-39. The binder resin is a polymer such as cellulosic materials. The binder may be dissolved in water or solvent (col. 3, lines 40-53, lines 59-63).

It is noted that Ignacio et al do not disclose that the sterilization-monitoring device monitors ethylene oxide sterilization. However, since the claims are directed to the device itself, Applicants' intended use is not sufficiently limiting to constitute a patentable distinction because the device claims are limited only by their structural components. Thus, Applicants' claims are anticipated because Ignacio et al teach a sterilization indicator having the same structural features as those claimed.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Ignacio et al in view of US Patent 6,395,551 to Kipke et al.

The disclosure of Ignacio et al is described above. Ignacio et al fail to teach the particular dyes recited in claim 4 of the instant invention.

Kipke et al teach indicators for sterilization. As pH sensitive dyes, the reference discloses the dyes taught by Ignacio et al (fluorescein, phenolphthalein) and those claimed by Applicants (bromothymol blue, bromocresol purple). Thus, Kipke et al provides for the equivalency between those dyes claimed and those taught by Ignacio et al. It would have been obvious to one of ordinary skill in the art to substitute the dyes of Ignacio et al for others (such as bromothymol blue and bromocresol purple) known to be pH sensitive dyes for sterilization monitoring. Such a modification would provide an indicator that allows sterilization to be monitored by observing color changes, alleviating the need for costly equipment and highly trained users.

Response to Arguments

6. Applicant's arguments with respect to claims 1-11 and 40-45 have been considered but are not considered persuasive for the following reasons: With respect to the anticipation rejection over Sumimoto et al, Applicants state that the reference requires the presence of a basic substance, which Applicants allege is the opposite of their invention. In response, the

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Examiner notes that the claims recite a monovalent cation and an anion. As monovalent cations, Applicants recite sodium, among others (claim 42 and 45). As anions, Applicants recite carbonate, among others (claims 43 and 44). Sumimoto et al teaches sodium carbonate as an activator. Thus, the reference is believed to teach the same as Applicants' claims.

With respect to the anticipation rejection over Ignacio, the Examiner does not understand Applicants' argument. Ignacio et al teach sterilization monitoring devices comprising a dye, a halogen source and a binder resin, wherein the halogen source is a compound such as an alkali metal halide salt (potassium bromide, for example). While the reference may not teach ethylene oxide sterilization, in particular, the device taught in Ignacio is the same as that claimed. The rejection is being maintained.

With respect to the obviousness rejection, Applicants argue that Ignacio is not available as a primary reference, but did not state any reasons as to why. With respect to the combination, Applicants argue that no motivation exists to combine the references. In response, the Examiner notes that modifying the Ignacio reference with the dyes of Kipke would provide an indicator that allows sterilization to be monitored by observing color changes, alleviating the need for costly equipment and highly trained users.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory

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period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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